This was not actually accepted and deemed filed by the FDA until late 1994 as Docket # 94P-0354/CP1.

**CITIZENS' PETITION PURSUANT TO 21 CFR 10.30 TO THE SECRETARY OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION**

Via Registered Mail, Return Receipt Requested
this _____ day of October, 1993

TO: Secretary Donna E. Shalala
Department of Health and Human Services
Public Health Services
200 Independence Ave SW 615F HHH
Washington DC 20201

Dr. David Kessler
c/o Dockets Management Branch
Food and Drug Administration
Center for Devices and Radiological Health
Department of Health and Human Services
5600 Fisher's Lane Rm 4-62
Rockville MD 20857

## A. ACTION REQUESTED

It is requested that the Commissioner of the Food and Drug Administration:

(1) Certify mercury/silver filling material (amalgam) and give a classification (I, II or III) pursuant to 21 CFR § 10.25, section 513(3) of the Act (21 U.S.C. 360 c(e)) and 21 CFR 860. Petitioners believe it should be in Class III, but in any event it should be given a classification.

(2) To require warnings be given to both dentists and patients - past, present and future - in regard to the toxicity of dental mercury and the hypersensitivity (allergic reaction) that it may also cause, pursuant to section 518 (a) of the Act [21 U.S.C. 360 h(a)(2)].

## B. STATEMENT OF GROUNDS

### CERTIFICATION

The 1976 Medical Devices Act as amended requires that all medical devices be certified and placed in either classification I, II or III. In 1978 the FDA Commissioner refused to exclude mercury/silver fillings (amalgam) from the definition as an implant. Federal Registry, vol. 43.146, July 28, 1978, page 32988.

In 1987 the FDA certified dental mercury (21 CFR 3700) in class I and amalgam alloy in class II.

The FDA maintains that mercury/silver fillings are a reaction product over which it has no jurisdiction, despite the fact that it has classified a number of other reaction products.

In January of 1993, the Public Health Service (PHS) presented the Final Report of the Committee to Coordinate Environmental Health and Related Programs (CCEHRP). This document was entitled "Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation", and included recommendations from several sub-committees. The recommendations for regulation were prepared by the Regulatory Work Group (Appendix VI), consisting of five officials of the Food and Drug Administration (FDA).

The recommendation of the Regulatory Work Group on dental amalgam, stated on page V1-2, was: "The Regulatory Work Group recommends that the Food and Drug Administration view dental amalgam as a kit, in that both mercury and alloy must be used together to create dental amalgam restorative material. FDA considers the class of the kit to be that of the component of the kit assigned the highest classification. In this case the kit would be viewed as a Class II device because that is the classification of amalgam alloy. No reclassification action would be required."

The full CCEHRP committee adopted this recommendation, as stated on page 19: "For this reason, a Regulatory Work Group (operating under the auspices of the Subcommittee on Risk Management) believes FDA should administratively combine dental mercury and amalgam alloys into a single product for regulatory purposes."

Also on page 19, the CCEHRP report stated: "Federal regulatory of dental amalgam and elemental mercury as an amalgam component resides with the Food and Drug Administration. Both products are regulated under the mandate of the Medical Device Amendments of 1976 and the Safe Medical Devices Amendments of 1990." The report further states: "Historically, FDA has regulated dental mercury and amalgam alloys separately, with mercury treated as a class I device and the alloy as a class II device."

Administrative combination of dental mercury and amalgam alloy, viewed as a "kit" without further evaluation or "reclassification action" of the subsequent reaction product as a distinct dental device, is a clear violation of the Rules and Procedures of the Food and Drug Administration for Medical Devices. Any Class II device must be subjected to "Performance Standards" in order to satisfy requirements to ensure "safety and effectiveness".

## WARNINGS

In the 52 Federal Register 30089, August 12, 1987 the FDA changed the classification of dental mercury, a component part mercury fillings, from the proposed Class II to Class I, stating, "... warnings under the misbranding provisions (21 U.S.C. 352) of the general controls of the act would warn dentists about the rare risk of allergic reactions among patients and the risk of toxicity to dental health professionals." Id.

Arriving at its conclusions that the risk of allergic reaction was "rare", the FDA relied on three (3) case reports, ignoring several other scientific studies clearly within the criteria set out in 21 C.F.R. 860.3, 860.7, for valid scientific evidence which showed that the risk of hypersensitivity (allergic) reaction to mercury effects at least five (5%) to eleven (11%) percent, and perhaps more, of those individuals receiving mercury fillings.

Since August 12, 1987 most manufacturers have failed to warn of the risk of allergic reaction as required under 21 U.S.C. § 352 and the FDA has failed to enforce them to do so under 21 U.S.C. § 334 and 21 C.F.R. § 800.55; thus, the respondent has failed to perform a duty owed to the petitioners and all the residents and citizens of the United States.

In ordering that warnings should be given to dentists of the risk of hypersensitivity, the respondent failed to comply with his duties set out by Congress in the Act under 21 U.S.C. 360 h(a)(2) which states, "An order under this subsection shall require that individual subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless ... notice ... would present a greater danger to the health of such individuals . . . ." The failure to give such notice presents an imminent hazard to those people who may be suffering from hypersensitivity, particularly in that hypersensitivity is often delayed until long after the placement of mercury fillings.

The respondent has further failed in his duties under the Act which goes on to state, "the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk." 21 U.S.C. § 360 h(a)(2)

## CONCLUSION

The FDA is requested to take immediate action or in the alternative to establish a special panel to consider this petition. The Dental Product Panel has shown by their past action

and inaction to be incapable of properly dealing with this issue. The new panel should be composed principally of experts with knowledge of toxicology, not dentistry. Since this is a most serious matter if the Secretary and Commissioner decline to take immediate action then they should not allow the normal time of 180 days for action on this petition. In that event, it is requested that the panel be appointed within 15 days and be directed to take action within 60 days. The most important information set out hereinafter and referenced in footnote number 1 was presented to the Commissioner in a letter of June 2, 1992 and much of the other information was previously presented to the FDA or contained in the Public Health Service Report of January, 1993, in which the FDA participated. Therefore a shortened time table is appropriate. All the information with the exception of a few unpublished papers is in the public domain and thus readily available to the FDA.

There is a great body of valid scientific literature impugning the safety of mercury/silver fillings[1].

(As the petitioners have no supplemental data sheet nor classification questionnaire, none is attached to this petition. If the FDA believe these are necessary and will be so kind as to send the appropriate forms, petitioners will attempt to complete them at a later date. If there are any technical defects in this petition the Secretary and the Commissioner are requested to notify petitioners and their counsel as soon as possible by telephone.)

Sam Ziff
Bio-Probe Inc
4401 Real Court
Orlando FL 32808

David C Kennedy DDS
51 Mill St Ste 4
Hanover MA 02339

Duane E Christian
810 M Nevada St
Carson City NV 89701

Douglas L Cook DDS
10971 Clinic Rd
Suring WI 54174

William W King III
1200 Rosewell Rd 2nd Floor
Marietta GA 30062

Michael F Ziff DDS
5025 Bermuda Circle
Orlando FL 32808

David W Ganong
2425 3rd Ave
San Diego CA 92101

Ed Arana DDS
PO Box 856
Carmel Valley CA 93924

Ed Arana DDS
107 Quien Sabe
Carmel Valley CA 93924

FAIM
Att: Howard G. Hindin DDS
Two Executive Blvd Suite 206
Suffern NY 10901

Howard Bellis
Ina Bellis Environmental Dental Assn
4801 Country Club Road
Vestal NY 13850

Joyal W Taylor DDS
9974 Scripps Ranch Blvd., #36
San Diego CA 92131

Mary N Boyd
PO Box 72666
Fairbanks AK 99707

Paul Gilbert DDS
123 Dunhams Corner Road
East Brunswick NJ 08816

Arline Brecher
1850 Golf View Court
Reston VA 22090

James W Medlock DDS
2326 S Congress Avenue 1D
West Palm Beach FL 33406

Scott J Loman DDS
416 Waverley Street Suite a
Polo Alto CA 94301

S Ward Eccles DDS
299 Juana #B
San Leandro CA 94577

Vaughn Harada DDS
Assn of Health Practitioner
PO Box 17990
Encino CA 91416-7990

Chris Norton
1533 St Frances Suite F
Santa Fe NM 87501

Louise Herbeck
4525 Statton Place
Downers Grove IL 60515

James Rota DDS
924 Westwood Blvd
Los Angeles CA 90024

Rick Paul
826 Shelby Street
Frankfort Ky 40601

Holly L Tincher
109 Woodford Village Drive
Versailles KY 40383

David Regiani, DDS
PO Box 458 ERvironmental Health
Ortonville MI 48462

Linda Price-King

Network, Inc.
PO Box 16267
Chesapeake VA 23328-6267

Robert O Stephenson
1837 No Way Lane
Fairbanks AK 99709

James Adams DDS
14513 S Bascom Avenue
Los Gatos CA 95032

Bob Lavely DDS
7300 New Lagrange Road
Louisville KY 40222

Leslie Cabrera
1930 Hillboro Avenue
Reno NV 89512

Karen R Hunter
P O Box 40876
Reno NV 89504-4876

Roger G Bidle
2305 Glendale Avenue
Sparks NV 89431

Mark A Breiner DDS
325 Post Road
Orange Ct 06477

Bernard L Montalbano DDS M ED
RR 14 Box 228
Santa Fe NM 87505

Murlene Brake
725-9 Tramway Lane NE
Albuquerque NM 87122

Paul G Rubin DDS
101 14th Ave E
Seattle WA 98112

Larry R Wilson

Harold J Kristal DDS
224 West Richmond Avenue
Point Richmond CA 94801

Michael F Brown
511 North Webster
Naperville IL 60563

David B Satterlee
1730 E Redbud Lane
Springfield MO 65803

Gary A Strong DDS
503 Wickes Lane #2
Billings MT 59105

Robert L Olson
1966 E Chapman Ave "D"
Fullerton CA 92631

Louis B Cerrone DMD
1703 E Valley Pwy Suite C
Escondido CA 92027

Jan C Ingelstrom
4668 Mountlake
Pocatello *ID* 83202

Marc D. Flack
931 E 4500 SO
Salt Lake City UT 84117

Ruth Scowcroft
3259 Harrison #8D
Ogden UT 84403

Sandra B Boyce
1283 E So Temple #501
Salt Lake City UT 84102

Laurie Gunkel

Route 2 Box AA68
Middlesboro KY 40965

3908 Brina Lane
Magna UT 84044

Glenda Thames
#1 Cedarwing
Woodlands TX 77380

Vandella Graven
4701 So 1065 West
Salt Lake City UT 84123

Fred Bonds DDS
1231 N Mission
Mt Pleasant MI 48858

Audrey E. Adams
1107 W 4800 S
Salt Lake City UT 84123-4433

Douglas Adams
1107 W 4800 S
Salt Lake City UT 84123-4433

Trina R Atwood
12828 So 4400 W
Riverton UT 84065

Sonya J Steiner
1107 W 4800 S
Salt Lake City UT 84123

Kim Michaeli
8047 S Angel Street
Sandy UT 84070

Stephanie Nelson
P O Box 253
Huntsville UT 84317

Mark Fitch
338 South 300 West
Kaysville UT 84037

Casandra Adkinson
1804 W Altair Circle
Salt Lake City UT 84116

Leslie M. Nixon
1949 E 2125 N
Layton UT 84040

Louise Whiteside
100 Plumtree Ln #20 I
Midvale UT 84047

Norma Zimmer
P O Box 2699
Park City UT 84060

Holly Bennett
931 E 4500 So
Salt Lake City UT 84117

Cande A Fitch
338 So 300 W
Kaysville UT 84037

Phillip P Sukel DDS
1640 N Arlington Hts Rd #201
Arlington Hts IL 60004

Dawne Stuart Gruher
5189 East Moore Rd
Salt Lake City UT 84117

Armand V de Felice
N 4703 Maple Street
Spokane WA 99205

Marcia Basciano DDS
2932 Finley Road
Downers Grove IL 60515

Matthias Luerken DDS
P O 5929
So Lake Tahoe CA 96157

Terry J Lee
4210 N 32nd Street
Phoenix AZ 85018

Stanley Ilin
215 E Hawaii
Nampa ID 83686

Ronald M Dressler DDS
3071 Campbellton RD SW
Atlanta GA 30311

Donald E Soli MD
708 North Center Street
Reno NV 89501

William Wesson DDS
119 S Spring
Aspen CO 81611

_____ _____
Signature Signature

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Print Name & Address Print Name & Address

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Print Name & Address Print Name & Address

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Print Name & Address Print Name & Address

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FDA Transcript Dental Products Panel Hearing 3/15/91.

pet-plfs

kennedy /misc

Petitioners are represented by and all correspondence should initially be directed to:

Robert E. Reeves
REEVES & GRADDY
167 W Main Street Ste 300
Lexington KY 40507-1396
(606) 252-8539

James S. Turner
SWANKIN & TURNER
1424 16th St. NW Suite 105
Washington DC 20036
(202) 462-8800